

## REMARKS

Claims 1-16 were pending in the instant application. Claims 3, 5, 6, 8-13, 15, and 16 were withdrawn from the Examiner as being directed to nonelected subject matter. Applicants have canceled claims 7 and 14 without prejudice and have amended claim 1 to incorporate subject matter from the canceled claims. Claim 2 has been amended for clarity by changing the article “an” to “the.” The claim amendments do not introduce any new matter and thus, their entry is requested. Upon entry of the present Amendment, therefore, claims 1, 2, and 4 will be pending and under examination in the instant application.

### Examiner's Previous Restriction Requirement

The Examiner acknowledged Applicants' election with traverse of Group II in paper No. 8. The Examiner has deemed the requirement proper and therefore made it final. Claims 3, 5, 6, 8-13, 15, and 16 were withdrawn from the Examiner as allegedly being directed to nonelected subject matter.

### Rejections Under 35 U.S.C. §112, first paragraph

The Examiner first stated that the citation of subject matter at page 5, lines 15-24 in the specification appears to be reference material that is essential for the practice of the instant invention, namely, NPY receptor antagonists. The Examiner then stated that the Applicant has not made a statement that these references have been incorporated by reference. The Examiner further asserted that even if such a statement had been made, it would be improper because the incorporated material is essential information that is included in nonpatent literature.

The Examiner then rejected claims 1, 2, 4, 7, and 14 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to convey to one skilled in the art that the inventor had possession of the invention at the time the

application was filed. The Examiner took the position that the specification fails to properly disclose or describe NPY receptor antagonists that would be used in the claimed methods. The Examiner acknowledged Applicants' reference in the specification to prior art, but contends that the "essential compounds" have not been described in the specification.

The Examiner also rejected claims 1, 2, 4, 7, and 14 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner asserted that the invention is not enabled because "one in the art can not use that which has not been described."

In response, Applicants respectfully traverse the Examiner's rejections under 35 U.S.C. §112, first paragraph. Applicants assert that the claims are both adequately described and fully enabled. At the outset, Applicants point out that the Examiner's assertion that a statement incorporating the publications by reference is absent is simply incorrect. Applicants direct the Examiner's attention to page 1, lines 13-15, which clearly provides such a statement.

Furthermore, Applicants maintain that referring to known antagonists that can be employed in the claimed methods is sufficient to describe and enable the claims. If a skilled artisan would know what the referenced subject matter is, then there is no failure to disclose material essential for the practice of the invention. The antagonists referred to at page 5 of the specification are merely some of the many antagonists known in the art before the date of the present invention. In fact, the Soppet, et al. reference cited by the Examiner elsewhere in the November 19, 2002 Office Action, illustrates the Applicants' point. If the Soppet, et al. reference discloses antagonists (as is the position of the Examiner), then such antagonists are known. To further emphasize this point, Applicants have conducted a search of the Chemical Abstracts database for citations concerning NPY antagonists prior to the August 25, 2000 filing date of the instant application. A copy of the search results is attached for the Examiner's convenience. As one can see, 993 citations were

uncovered in the search. Moreover, a previous search concerning NPY receptor agonists or antagonists, conducted in the same database and relating to documents published before December 19, 1997, yielded 909 citations. That search then was restricted to the Y1, Y2, and Y5 receptors, which still yielded 302 citations. Applicants have attached the abstracts and bibliographic data of the 20 publications published most immediately prior to December 19, 1997. The results of these searches indicate the extensive knowledge in the art of receptor active agents, especially antagonists, available prior to the filing of the present application. Accordingly, Applicants maintain that the specification, which refers to examples of NPY antagonists known in the art, fully describes and enables the claimed invention. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §112.

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 1, 2, and 4 under 35 U.S.C. §102(b) as allegedly being anticipated by Soppet, et al. (WO 96/34877). The Examiner stated that Soppet, et al. discloses a method of treating a patient with inhibitors of NPY receptors.

In response, without conceding the correctness of the Examiner's position, but to advance prosecution of the subject application, Applicants have amended claim 1 to recite "a method for reducing the overproduction of neuropeptide Y (NPY) in an individual, said method being aimed to modulate an overactive NPY system in said individual, wherein the overproduction of NPY is caused by a polymorphism comprising the substitution of the position 7 leucine for proline in the signal peptide part of the human preproNPY." Applicants assert that the amendment to claim 1 obviates the Examiner's rejection of claims 1, 2, and 4, as the Soppet, et al. reference fails to disclose all limitations of the claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §102(b).

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 7, and 14 under 35 U.S.C. §103(a) as allegedly being obvious over Soppet, et al. and Koulu, et al (U.S. Patent No. 6,046,317). The Examiner stated that Soppet, et al. teaches the inhibition of NPY receptor via NPY receptor antagonists, and that abnormal conditions such as obesity can be treated with NPY receptor inhibitors. The Examiner further stated that Koulu, et al. teaches a screening method for diagnosing a predisposition for increased serum cholesterol or LDL cholesterol levels in a human by detecting a position 7 leucine for proline mutation in NPY. The Examiner concluded that it would have been obvious to treat conditions caused by overproduction of NPY by administering NPY receptor antagonists, based on Soppet, et al.'s reference to controlling NPY receptor activity by inhibiting NPY receptors and Koulu, et al.'s reference to a method for diagnosing a predisposition to such conditions by detecting the above polymorphism.

In response, Applicants respectfully traverse the Examiner's rejection. Applicants have canceled claims 7 and 14 as noted above. Applicants maintain that claims 1 and 2, as amended, are not obvious over the cited art. The Koulu, et al patent refers to a relationship between increased serum cholesterol and substitution of the position 7 leucine for proline in the signal peptide part of the human preproNPY. The Koulu patent does not disclose or suggest that there would be any relationship between overproduction of NPY and this substitution. Such a finding was the result of additional research, which is disclosed in the instant application. Following the teachings of the Koulu patent, (even if combined with the Soppet et al. reference as the Examiner has done), one could not reasonably conclude either that the substitution of the position 7 leucine for proline in the signal peptide part of the human preproNPY, would lead to a) overproduction of NPY, b) decreased production of NPY or c) unchanged production of NPY. Therefore, claims 1 and 2 are not obvious over the references cited by the Examiner. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 2, 7, and 14 under 35 U.S.C. §103(a).

Serial No. 09/645,590

March 19, 2003

Page 7

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes, are patentable over the prior art, and fully address the Examiner's concerns as set forth in the November 19, 2002 Office Action. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

RESPECTFULLY SUBMITTED,					
NAME AND REG. NUMBER	Patrick T. Skacel, Reg. No. 47,948				
SIGNATURE				DATE	March 19, 2003
Address	ROTHWELL, FIGG, ERNST & MANBECK, pc 1425 K Street, N.W., Suite 800				
City	Washington	State	D.C.	Zip Code	20005
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031

Attachments: Marked-up Copy of Amended Claims  
Database search results

106A.am1

**Marked-Up Copy of the Amended Claims**

1. (Amended) A method for reducing the overproduction of neuropeptide Y (NPY) in an individual, said method being aimed to modulate an overactive NPY system in said individual, wherein the overproduction of NPY is caused by a polymorphism comprising the substitution of the position 7 leucine for proline in the signal peptide part of the human preproNPY.
  
2. (Amended) The method according to claim 1 wherein [an]the overproduction of NPY is counteracted by administering an antagonist to said individual.